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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,546	01/18/2002	Gregory A. Demopoulos	OMER118473	6615

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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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04/16/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

Office Action Summary	Application No. 10/031,546	Applicant(s) DEMOPULOS ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,39,44-51,53,73-76 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38, 39, 44-51, 53, 73, 74-76 and 81-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 12/23/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38, 39, 44-51, 53, 73, 74-76 and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable the combined disclosures of Glorioso et al (USPN 6,413,511 hereafter '511).

The '511 patent discloses a method of regenerating joint cartilage by intra-articular injection of composition comprising compounds that both promote chondrocyte anabolism and inhibit chondrocyte catabolism (col. 6, lin. 3-10). The method of treating full thickness mammalian cartilage defects includes injecting synovial cells and chondrocyte cells that express interleukins and transforming growth factors such as beta 1, 2 or 3, where the delivery is made intra-articularly into the joint space and alleviates the defect (col. 14, lin. 28-44, col. 20, lin. 10-33). Other compounds such as those that inhibit nitric oxide synthase can also be produced (col.

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23, lin. 35-42). The synovial cells and chondrocyte cells are first infected with a DNA fragment that expressed the respective compounds, next the expressing cells are injected into the joint space (abstract). These modified cells directly promote or inhibit anabolic and catabolic activities. The combination formulation both promotes matrix synthesis and inhibits matrix breakdown (col. 28, lin. 10-20). The concentrations of each compound are carefully monitored in order to not have too much matrix formation and not enough degeneration inhibition (*Ibid.*). The formulation can be in the form of a gel solution (claim 14). The formulations of the patent are applied to any full thickness articular defect such as arthritis. Arthritis is a chronic disorder that causes various injuries to the joints and surrounding tissue. The formulation of the reference is useful against such conditions alleviating the defects caused by arthritis (Example XIII). As such it would have been obvious to apply the formulation to either prevent or treat arthritis and its associated traumas and defects to joint and cartilage (Examples).

The reference does not specifically exemplify a formulation comprising the combination of compounds recited in the claims however the disclosures indicate that the formulation intends to both promote anabolic activity while inhibiting cartilage catabolism. Further the formulation comprising both modified synovial cells and chondrocytes, where each cell can comprise different compounds. It would have been obvious to include a DNA fragment that promotes anabolic activity and another DNA fragment that inhibits catabolic activity in order to be more effective in treating defects.

With these things in mind it would have been obvious to treat a wide range of degenerative disorders include arthritis. One ordinary skill in the art would have been motivated to treat damaged cartilage before or after injury in order to provide the desired treatment.

Response to Arguments

Applicant's arguments with respect to claims 38, 39, 44-51, 53, 73, 74-76 and 81-83 have been considered but are moot in view of the new ground(s) of rejection. The newly applied art addresses the new "directly promotes cartilage anabolic processes" where the formulation comprises modified cells that express anabolic compounds and catabolic inhibitors. The previous prior art dealt with the injection of DNA to induce the expression of the compound, while the new art applies the expressing modified cells into the defective area, using the cells as carriers for the compounds.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Specifically the '511 patent addresses the "directly promotes cartilage anabolic processes" limitation by injecting modified cells that express the compounds of the instant claims such as interleukins nitric oxide synthase inhibitors and members of the transforming growth factor super family. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618